PATENT COOPERATION TREATY

From t	he NATIONAL SEARCHING AUTHO	DRITY			REC'D 27 MAY 2005
To:	ļ.	1/8		PCT	WIPO P
	see form PCT/ISA/220		INTERNATION		IING AUTHORITY
			(1-	PCT Rule 43 <i>b</i>	<i>n</i> s. 1)
i			Date of mailing (day/month/year) see	e form PCT/ISA/210	(second sheet)
	cant's or agent's file reference form PCT/ISA/220	•	FOR FURTHER A See paragraph 2 belo	w	
	national application No. /US2005/001457	International filing date (day/month/year)	Priority date (day) 16.01.2004	/month/year)
	national Patent Classification (IPC) or K3/04	both national classification	and IPC		
Appli UNI	icant VERSITY OF FLORIDA RESE	ARCH FOUNDATIO	N, INC.	-	
1.	☐ Box No. IV Lack of unity of Box No. V Reasoned sta	pinion ment of opinion with reg of invention tement under Rule 43 <i>b</i> itations and explanation	gard to novelty, inventi is.1(a)(i) with regard to ns supporting such sta	novelty, inventive	•
	☐ Box No. VIII Certain defect ☐ Box No. VIII Certain obser				
2.	FURTHER ACTION If a demand for international prewritten opinion of the Internation the applicant chooses an Author International Bureau under Rule will not be so considered. If this opinion is, as provided at submit to the IPEA a written remonths from the date of mailing whichever expires later.	eliminary examination is nal Preliminary Examini rity other than this one e 66.1 bis(b) that written bove, considered to be	s made, this opinion wing Authority ("IPEA"). to be the IPEA and the opinions of this internal written opinion of the repriate, with amendm	However, this doe of chosen IPEA ha ational Searching IPEA, the applica ents, before the e	es not appry where is notified the Authority ant is invited to expiration of three
3.	For further options, see Form F For further details, see notes to				
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	me and mailing address of the ISA:		Authorized Officer		



European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016

de Bakker, M

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2005/001457

	Box	No.	I Basis of the opinion
1.	With the la	rega angu	ard to the language, this opinion has been established on the basis of the international application in uage in which it was filed, unless otherwise indicated under this item.
	1	lang	s opinion has been established on the basis of a translation from the original language into the following puage , which is the language of a translation furnished for the purposes of international search der Rules 12.3 and 23.1(b)).
2.	With nece	reg essa	ard to any nucleotide and/or amino acid sequence disclosed in the international application and rry to the claimed invention, this opinion has been established on the basis of:
	a. ty	pe o	of material:
		3 8	a sequence listing
] t	table(s) related to the sequence listing
	b. fo	rma	at of material:
		j i	in written format
	C	3 i	in computer readable form
	c. tir	me d	of filing/fumishing:
		J (contained in the international application as filed.
	E	J 1	filed together with the international application in computer readable form.
			furnished subsequently to this Authority for the purposes of search.
3	. 🗆	has	addition, in the case that more than one version or copy of a sequence listing and/or table relating theretos been filed or furnished, the required statements that the information in the subsequent or additional bies is identical to that in the application as filed or does not go beyond the application as filed, as propriate, were furnished.
4	. Add	litior	nal comments:
-	Box	x No	o. II Priority
1	. 🗵	do	e validity of the priority claim has not been considered because the International Searching Authority es not have in its possession a copy of the earlier application whose priority has been claimed or, where quired, a translation of that earlier application. This opinion has nevertheless been established on the sumption that the relevant date (Rules 43 <i>bis</i> .1 and 64.1) is the claimed priority date.
2	2. 🗆	ha	is opinion has been established as if no priority had been claimed due to the fact that the priority claim is been found invalid (Rules 43 <i>bis.</i> 1 and 64.1). Thus for the purposes of this opinion, the international ing date indicated above is considered to be the relevant date.
3	. Add	ditio	nal observations, if necessary:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, Inventive step or Industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

1,3-8,10-21

No: Claims

2,9,22

Inventive step (IS)

Yes: Claims

No: Claims

1-22

Industrial applicability (IA)

Yes: Claims

1-22

No: Claims

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item VIII

Certain observations (Clarity)

- The application does not meet the requirements of Article 6 PCT, because **claims 1**, **2**, **16**, **21**, **22** are not clear.
- 1.1 Although claims 1, 2 have been drafted as separate independent claims in the same category, they appear to relate effectively to the same subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT. The same holds for the independent use claims 21, 22.
 - Claims 1, 2, 21, 22 are therefore not clear (Article 6, PCT).
- 1.2 Furthermore, claim 1 describes a TTI system comprising (multiple) time temperature integrators, all having a zero-order decay reaction rate mechanism according to the same equation. The application (description: page 15, lines 7-11), however, describes a system with two TTI's having different reaction rate mechanisms. Claim 1 is therefore not supported by the description.
- 1.3 The clarity problem in **claim 16** relates to points c) and d) of the method. For the skilled person, it is not clear how safety of fresh food can be monitored by observing and comparing the *rates* of change of the TTI's.
 - In the description (page 10, line 36 page 11, line 6) is suggested that not only the rate of change is observed, but also the change itself. Further, in the passage cited above, only the changes (and not the rates) are compared in order to monitor food safety. This interpretation is confirmed on page 15 (lines 19-35).

In conclusion, **claim 16** in its present form (i.e. comparing rates of changes) is not supported by the description and is therefore not clear (Article 6, PCT). In the rest of this Written Opinion it is assumed that in **claim 16**, the change (instead of the rate of change) is observed and compared.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Documents

2 Reference is made to the following documents:

D1: US-A-6 113 857 (MANICO ET AL) 5 September 2000

D2: WELT B A, SAGE D S, BERGER K L: "Performance Specification of Time-temperature Integrators Designed to Protect Against Botulism in Refrigerated Fresh Foods" JOURNAL OF FOOD SCIENCE, vol. 68, no. 1, 2003, pages 2-9, XP002328450

D3: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE,
PHILADELPHIA, PA, US; September 1998 (1998-09), SKINNER GUY E ET AL:
"Conservative prediction of time to Clostridium botulinum toxin formation for use
with time-temperature indicators to ensure the safety of foods" XP002328442
Database accession no. PREV199800447221

Novelty

- The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 2, 9, 22** is not new in the sense of Article 33(2) PCT.
- 3.1 Document D1 discloses (the references in parentheses applying to this document):

An improved fresh food and perishable products monitoring system comprising time temperature integrators comprising a reaction rate mechanism having a reaction rate constant (Col.1, lines 13-18; Col.2, lines 17-24);

wherein the reaction rate mechanism exhibits temperature sensitivity (Col.2, lines 19-21);

wherein the reaction rate mechanism decays when exposed to temperature (Col.4, lines 3-9);

wherein the improvement comprises a reaction rate mechanism approximated by reaction kinetic schemes (Col.7, lines 26-34).

The subject-matter of **claim 2** and, mutatis mutandis, independent use **claim 22** is therefore not new (Article 33(2) PCT).

3.2 Document D1 discloses further:

a system of time temperature integrators wherein the TTI's have different temperature sensitivities (Col.2, lines 19-21) as in claim 9.

The subject-matter of claim 9 is therefore not new (Article 33(2) PCT).

Inventive Step

The above-mentioned lack of clarity notwithstanding, the subject-matter of **claims 1**, **3-8**, **10-21** does not involve an inventive step in the sense of Article 33(3) PCT, and therefore the criteria of Article 33(1) PCT are not met.

INDEPENDENT CLAIMS

- 4.1 The reaction rate mechanism according to the equation given in **claim 1** is known from document D2 (see the paragraph on "Predictive modelling"). A system of multiple TTI's is described in document D1 (see the passages cited in the corresponding Search Report). The subject matter of **claim 1** (and independent use **claim 21**) is therefore anticipated by the combination of D1 and D2 and does not involve an inventive step (Article 33(3) PCT).
- 4.2 Independent method claim 16 (referring back to claim 1) is also anticipated by the combination of D1 (comparing the readings from multiple TTI's: Col.7, lines 19-25) and D2 (i.e. the TTI described in claim 1). The subject matter of claim 16 therefore does not involve an inventive step (Article 33(3) PCT).

DEPENDENT CLAIMS

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No.

PCT/US2005/001457

4.3 Dependent claims 3-8, 10-15, 17-20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see documents D1-D3 and the corresponding passages cited in the search report.

PATENT COOPERATION TREATY

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see form PCT/ISA/220			WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY		
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	eant's or agent's file reference form PCT/ISA/220		FOR FURTHER A		
	ational application No. /US2005/001457	International filing date ((day/month/year)	Priority date (day/mont 16.01.2004	h/year) ·
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Name and mailing address of the ISA



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de Bakker, M

Telephone No. +31 70 340-4759



WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2005/001457

	ox No. I Basis of the opinion
1.	lith regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
	This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2.	Vith regard to any nucleotide and/or amino acid sequence disclosed in the international application and ecessary to the claimed invention, this opinion has been established on the basis of:
	type of material:
	□ a sequence listing
	☐ table(s) related to the sequence listing
	o. format of material:
	☐ in written format
	☐ in computer readable form
	c. time of filing/furnishing:
	☐ contained in the international application as filed.
	☐ filed together with the international application in computer readable form.
	☐ furnished subsequently to this Authority for the purposes of search.
3.	In addition, in the case that more than one version or copy of a sequence listing and/or table relating theref has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4.	Additional comments:
_	Box No. II Priority
1	The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2	□ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43 bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3	Additional observations, if necessary:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2005/001457

Box No. V Reasoned statement under Rule 43bis.1(a)(l) with regard to novelty, Inventive step or Industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

1,3-8,10-21

No: Claims

2,9,22

Inventive step (IS)

Yes: Claims

No: Claims

1-22

1-22

Industrial applicability (IA)

Yes: Claims

No: Claims

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item VIII

Certain observations (Clarity)

- The application does not meet the requirements of Article 6 PCT, because **claims 1**, **2**, **16**, **21**, **22** are not clear.
- 1.1 Although claims 1, 2 have been drafted as separate independent claims in the same category, they appear to relate effectively to the same subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT. The same holds for the independent use claims 21, 22.

Claims 1, 2, 21, 22 are therefore not clear (Article 6, PCT).

- 1.2 Furthermore, **claim 1** describes a TTI system comprising (multiple) time temperature integrators, all having a zero-order decay reaction rate mechanism according to the same equation. The application (description: page 15, lines 7-11), however, describes a system with two TTI's having different reaction rate mechanisms. **Claim 1** is therefore not supported by the description.
- 1.3 The clarity problem in **claim 16** relates to points c) and d) of the method. For the skilled person, it is not clear how safety of fresh food can be monitored by observing and comparing the *rates* of change of the TTI's.

In the description (page 10, line 36 - page 11, line 6) is suggested that not only the rate of change is observed, but also the change itself. Further, in the passage cited above, only the changes (and not the rates) are compared in order to monitor food safety. This interpretation is confirmed on page 15 (lines 19-35).

In conclusion, **claim 16** in its present form (i.e. comparing rates of changes) is not supported by the description and is therefore not clear (Article 6, PCT). In the rest of this Written Opinion it is assumed that in **claim 16**, the change (instead of the rate of change) is observed and compared.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Documents

- 2 Reference is made to the following documents:
 - D1: US-A-6 113 857 (MANICO ET AL) 5 September 2000
 - D2: WELT B A, SAGE D S, BERGER K L: "Performance Specification of Timetemperature Integrators Designed to Protect Against Botulism in Refrigerated Fresh Foods" JOURNAL OF FOOD SCIENCE, vol. 68, no. 1, 2003, pages 2-9, XP002328450
 - D3: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; September 1998 (1998-09), SKINNER GUY E ET AL: "Conservative prediction of time to Clostridium botulinum toxin formation for use with time-temperature indicators to ensure the safety of foods" XP002328442 Database accession no. PREV199800447221

Novelty

- The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 2, 9, 22 is not new in the sense of Article 33(2) PCT.
- 3.1 Document D1 discloses (the references in parentheses applying to this document):

An improved fresh food and perishable products monitoring system comprising time temperature integrators comprising a reaction rate mechanism having a reaction rate constant (Col.1, lines 13-18; Col.2, lines 17-24);

wherein the reaction rate mechanism exhibits temperature sensitivity (Col.2, lines 19-

wherein the reaction rate mechanism decays when exposed to temperature (Col.4, lines 3-9);

wherein the improvement comprises a reaction rate mechanism approximated by reaction kinetic schemes (Col.7, lines 26-34).

The subject-matter of **claim 2** and, mutatis mutandis, independent use **claim 22** is therefore not new (Article 33(2) PCT).

3.2 Document D1 discloses further:

a system of time temperature integrators wherein the TTI's have different temperature sensitivities (Col.2, lines 19-21) as in **claim 9**.

The subject-matter of claim 9 is therefore not new (Article 33(2) PCT).

Inventive Step

The above-mentioned lack of clarity notwithstanding, the subject-matter of **claims 1**, **3-8**, **10-21** does not involve an inventive step in the sense of Article 33(3) PCT, and therefore the criteria of Article 33(1) PCT are not met.

INDEPENDENT CLAIMS

- 4.1 The reaction rate mechanism according to the equation given in **claim 1** is known from document D2 (see the paragraph on "Predictive modelling"). A system of multiple TTI's is described in document D1 (see the passages cited in the corresponding Search Report). The subject matter of **claim 1** (and independent use **claim 21**) is therefore anticipated by the combination of D1 and D2 and does not involve an inventive step (Article 33(3) PCT).
- 4.2 Independent method claim 16 (referring back to claim 1) is also anticipated by the combination of D1 (comparing the readings from multiple TTI's: Col.7, lines 19-25) and D2 (i.e. the TTI described in claim 1). The subject matter of claim 16 therefore does not involve an inventive step (Article 33(3) PCT).

DEPENDENT CLAIMS

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No.

PCT/US2005/001457

4.3 Dependent claims 3-8, 10-15, 17-20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see documents D1-D3 and the corresponding passages cited in the search report.